

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P., and DEY, INC.

Defendants.

C.A. No. 06-113 (JJF)

C.A. No. 06-604 (JJF)

CONSOLIDATED

SEPRACOR INC.,

Plaintiff,

v.

BARR LABORATORIES, INC.,

Defendant.

C.A. No. 07-438 (JJF)

**SEPRACOR'S REPLY BRIEF IN SUPPORT OF ITS
MOTION TO CONSOLIDATE THE DEY AND BARR CASES**

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February 29, 2008

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INTRODUCTION

Barr and Dey's answering briefs present no compelling reason why these cases, involving the same five patents and similar if not identical issues, should be the subject of two separate trials. Although Barr captioned its answering brief as an "opposition," Barr agrees that consolidation is appropriate and offers for the Court's consideration an alternative case schedule, which Sepracor does not oppose. Dey argues that consolidation is inappropriate on the bald assertion that it would somehow delay the commercialization of its products. This is incorrect and ignores the fact that Breath has sole ANDA "first-filer" status for all commercially relevant products at issue. For the reasons explained in Sepracor's opening brief and below, this Court should consolidate the Barr and Dey cases for all purposes, including a single bench trial.

ARGUMENT

Neither Barr nor Dey deny that it is most efficient for this Court to hear similar, if not identical issues, involving the same patents in a single trial. Nor can they deny that hearing the cases together will have little impact on the current schedule (where no Markman briefs have been filed and no Markman hearing, pretrial conference or trial date is even set), or have any impact on the commercial introduction of their generic products.

Barr *agrees* that the Dey and Barr cases should be consolidated. Barr only requests that the consolidated schedule proposed by Sepracor be extended by one month, which Sepracor does not oppose,¹ and seeks modifications on the discovery deposition limits Sepracor proposed.²

¹ As a condition of its proposed consolidated schedule, Barr requests that it be provided access to the relevant documents from the Breath and Dey cases. [C.A. No. 07-438-JJF, D.I. 48 at 3-4.] Sepracor has agreed to produce these documents. To date, Sepracor has produced over 500,000 pages of documents to Barr and many of the transcripts of
(Continued . . .)

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Dey, on the other hand, opposes consolidation based primarily on the argument that market entry of its proposed generic concentrate solution would be delayed.³ This is a red herring. Dey's proposed concentrate solution is relatively insignificant compared to the other dosage strengths it seeks to sell – the concentrate makes up only 2 to 3% of the total sales for Sepracor's Xopenex® inhalation solution products. [Exh. 1.]⁴ Indeed, the other ANDA filers, Breath, Barr, and Watson (who did not challenge the five method of use patents and therefore was not sued), view the concentrate as less commercially significant because none of these other generic challengers filed an ANDA seeking approval to sell the concentrate.

Dey concedes that the 30-month stay for its proposed generic concentrate solution does not expire until February 2009. In positing that if "judgment favorable to Dey is rendered in August 2008, Dey could go to market with the concentrate solution in August 2008" (D.I. 255 at 8), Dey fails to acknowledge that no Markman hearing, pretrial conference or trial date has

(. . . continued)

depositions taken by Dey and Breath. By the end of the week, Sepracor will produce pursuant to D. Del. LR 26.2 the transcripts of all of the depositions taken by Dey and Breath as well as its claim construction briefs from the Breath case. Sepracor will continue to produce on a rolling basis the relevant document productions, expert reports, and discovery responses from the Breath and Dey cases.

² Sepracor continues to believe that Barr should be limited to a total of 50 hours for fact depositions. In the spirit of cooperation, Sepracor advised Barr during a February 27, 2008 teleconference that it would agree to a half-day of deposition (3.5 hours) for any witness that has already been deposed in either the Breath or Dey cases.

³ There is no dispute that Breath has sole ANDA "first filer" status for the 0.31 mg/3 mL, 0.63 mg/3 mL, and 1.25 mg/3 mL commercial presentations of Xopenex®. Likewise, there is no dispute that Dey has sole ANDA "first filer" status for the fourth commercial presentation of Xopenex®, 1.25 mg/0.5 mL, referred to as the "concentrate."

⁴ "Exh. ____" refers to exhibits attached to the accompanying February 29, 2008 Declaration of Preston K. Ratliff II.

even been set, making the prospect of a final judgment in August 2008 (or indeed anytime prior to February 2009) exceedingly unlikely.

Dey's argument that consolidation will delay market entry of the three most commercially significant product strengths that it seeks to sell also is incorrect. As Sepracor explained in its opening brief, Breath's sole ANDA first-filer exclusivity prevents Dey from marketing until six months (180 days) after Breath first markets its products. [D.I. 254 at 3-4.]⁵ Dey suggests that a decision by this Court could create a forfeiture of Breath's first-filer exclusivity and therefore allow Dey to market its products sooner. [D.I. 255 at 8-9.] This is wrong. As Dey admits in its brief (at page 9), Dey could only cause a forfeiture of Breath's first-filer exclusivity if Dey received a decision of patent invalidity or non-infringement with respect to each patent that Breath has challenged.⁶ This is impossible for Dey because the Dey case does not involve Sepracor's '289 patent, which is at issue in the Breath case.

Further, although Dey devotes an entire section of its brief to emphasizing that this is a Hatch-Waxman case (D.I. 255 at 6-7), it fails to refute the large body of Hatch-Waxman case law Sepracor cites where cases such as these have been consolidated. [D.I. 254 at 5-6.]

⁵ Unless specified otherwise, all "D.I." references herein refer to the document index number in the Dey case, C.A. No. 06-113-JJF.

⁶ The Hatch-Waxman Act provides Breath with 180 days of exclusivity by specifying that Dey's ANDA (and Barr's ANDA) "shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant," *i.e.*, Breath. 21 U.S.C. § 355(j)(5)(B)(iv)(I). Breath's 180 day exclusivity can only be forfeited under conditions specified in the statute, most notably if "***as to each of the patents*** with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), ... a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (emphasis added). Breath submitted paragraph IV certifications on the five patents at issue in the Dey and Barr cases as well as Sepracor's '289 patent.

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Instead, Dey relies on four distinguishable cases that involve neither the Hatch-Waxman Act, nor are even patent cases. [D.I. 255 at 10.] For example, in *La Chemise Lacoste v. The Alligator Co., Inc.*, 60 F.R.D. 164 (D. Del. 1973), the court held that consolidation was not appropriate because the first case had been pending for over three years and was ready for trial while the second case had only recently been filed. Further, the first case involved seven distinct issues of law and fact while the second case involved three separate and distinct issues. *Id.* at 175. Unlike *La Chemise Lacoste*, the Dey and Barr cases involve similar infringement issues and identical validity and enforceability issues, and the timing of the cases is much closer.

In *Mills v. Beech Aircraft Corp., Inc.*, 886 F.2d 758 (5th Cir. 1989), the Fifth Circuit upheld a district court's denial of consolidation because consolidation was not requested until eight months after the final pretrial order was filed in the first action. *Id.* at 762. Here, no final pretrial preparations have been scheduled.

In *Lewis v. Four B Corp.*, 347 F. Supp. 2d 1017 (D. Kan. 2004), the court declined to consolidate because the two cases only shared one common issue of law or fact. *Id.* at 1020. The first case involved only an allegation of race discrimination taking place in 2003 while the later case involved allegations of race, color, and sex discrimination taking place in 2004. *Id.* at 1019.

In *St. Bernard Gen. Hosp., Inc. v. Hosp. Service Assoc. of New Orleans, Inc.*, 712 F.2d 978 (5th Cir. 1983), the Fifth Circuit upheld a district court's denial of consolidation because the first case had been pending for *over a decade* and was ready for trial while the second case was still in the discovery phase. *Id.* at 990.

Dey also argues that Judge Thyng previously considered and rejected consolidation of the Dey and Barr cases. [D.I. 255 at 12.] The proposal before Judge Thyng,

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however, related only to consolidating the Markman proceedings in these cases, and not consolidating them for all purposes as requested here. [D.I. 207 at 17:18 – 18:1.]

Finally, Dey argues that Sepracor somehow delayed expert depositions because Sepracor took its first deposition of a Dey expert on February 22, 2008. Dey's argument makes no sense. As Sepracor explained to Dey in January and again in early February, expert depositions in the Breath case overlap with the current expert deposition period in the Dey case. [Exhs. 2-3.] In fact, **both** parties proposed dates in early February for expert depositions, and as is often the case, **both** parties were unable to take the depositions on these early dates. Sepracor took its first deposition of a Dey expert on February 22, 2008 and Dey took its first deposition of a Sepracor expert nearly a week later, on February 28, 2008. Again, Dey's claim that Sepracor has delayed makes no sense where, as explained above, the progress of this case is irrelevant to the market entry of Dey, or any other generic for that matter.

CONCLUSION

For the foregoing reasons and those set forth in Sepracor's opening brief, Sepracor respectfully requests that the Court consolidate the Barr and Dey cases for all purposes.

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February 29, 2008

CERTIFICATE OF SERVICE

I, hereby certify that on February 29, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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